MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : KANSAS CITY FIELD OFFICE (KAN-FO

DATE: 6/8/79

Re: Syntex Agribusiness, Inc.
Nutrition & Chemicals Div.
Verona, Mo.

TES

Site: ~~Syntex-Verona~~
ID#: MOD007452154
Break: 17.1
Other: 0751
6.8.79

FROM : TED L. ANDERSON, RIC
SPRINGFIELD RESIDENT POST

SUBJECT: Flash Flooding of Syntex Manufacturing Plant

On 6/7/79, Walter R. Friedhofen, Quality Assurance Manager, for Syntex Agribusiness, Inc., called the Resident Post to report that the firm's Verona plant had been hit by a flash flood, which had resulted in damage of some raw materials and manufacturing equipment. The Verona plant is a basic manufacturer of food and feed-grade propionates, Calcium Pantothenates, Beta Alanine, EDDI and pharmaceutical-grade Choline salts.

Kansas City District Office
June 18, 1979

TO: KAN-FO Files

We will continue to monitor water-damaged material.

Terry R. Winchell

Terry R. Winchell, Acting
Supervisory Investigator

TRW:ak

cc: SPG RP
: DIB
: IBRF
: HFO-510
sent 7/26/79 ak

On 6/8/79, I visited the Verona plant to assess the damage and determine the firm's intentions with respect to flood-damaged products. Upon arrival at the firm, credentials were shown and FD-482, Notice of Inspection, was issued to Production Superintendent Mike Deiker. Credentials were also shown to Mr. Friedhofen, and both gentlemen accompanied me on a tour of affected areas.

The flash flood was caused by locally heavy rains upstream from the plant. The Spring River runs just across the road west of the 100-acre plant site. There are some 18 buildings at this location, but most were unaffected by flash flooding since the water level was only approximately two feet high. There were two manufacturing buildings which received significant water damage. These areas are designated V-19 and V-10, and house propionate drying and Choline salts manufacturing, respectively. Water levels were about two feet in these buildings, and the most significant damage was to electric motors which had been submerged. No flooding occurred in the firm's finished-product warehouse, since it is on a slab well above grade; however, some finished products stored in Building V-10 and Building V-19 sustained water damage.

Since the firm was in the initial stages of cleanup during my visit, and all products were not accessible, I did not get an accurate inventory of what water damaged products there were. Not all pallets of products were examined for product contamination; however, all products were scheduled to be moved to a quarantine area. "HOLD" stickers had been placed on water-damaged lots.

In Building V-19, there were approximately 30/150-pound fiber drums of food-grade Calcium Propionate present which had been sitting on the floor or on pallets. Not all drums were full, some contained in-process material. Drums which I examined were not Poly-lined, and water had easily penetrated the drums.

Propionates are dried on a double-drum roller drier in this building. The auger located at one end of the drier was wet, as were augers used to convey product into the drums. Some bagged filtering agents also received water damage in this area.

Most of the products stored in Building V-10 were components (raw materials) and were present in various types of containers, including unlined paper bags. Products were stored on pallets, and generally the bottom two or three layers of bags appeared to be the only ones suffering water damage. The following products are an estimate of the amounts subjected to flood water in this building:

Product	Lot Size	Damage (Est.)	Container
Calpan 160	96/50-lb. bags	24/50-lb. bags	Paper bag
Calcium Chloride	175-80-Lb. bags	35-80-lb. bags	Paper bags (unlined)
Tartaric Acid BCC	105-100-lb. bags	15/100-lb. bags	Poly bag inside woven plastic bag
Tartaric Acid (Spain)	--	9/50-kg. drums	wooden drums
Tartaric Acid (Italy)	5 pallets	30/50-kg. drums	Poly bag inside woven plastic bag
Citric Acid (Pfizer)	51/100-lb. bags	16/100-lb. bags	unlined paper bags
Metallic Iodine	--	10/50-kg. drums	wooden drums
Beta Alanine	19 pallets	152/100-lb. bags	paper bags

At the conclusion of this visit, I advised Mr. Deiker that product-contact surfaces of manufacturing equipment had been exposed to flood waters, and that in addition to the firm's cleanup with a high-pressure spray, the equipment should also be sanitized. Mr. Deiker and Mr. Friedhofen stated that this would be done. Mr. Friedhofen stated that all affected lots would be removed from the manufacturing areas and would be quarantined. I requested that the firm inventory affected products and maintain documentation regarding disposition of them. As of the date of my initial visit, no decision had been made in this regard, since the firm's primary concern was to get back into production.

On 6/12/79, I contacted Mr. Friedhofen to determine the status of the affected areas. He stated that the firm had obtained sufficient sanitizing agents, and this was being done. All affected materials have been removed to a separate building and have been quarantined, and inventory is being taken. No decision has yet been made regarding rework or segregation of the products involved.

I informed Mr. Friedhofen that I wished to monitor the firm's activities in this regard, particularly with respect to any rework material. I also informed Mr. Friedhofen that I wanted to witness the destruction of any products destroyed. Mr. Friedhofen stated that as soon as a decision was made regarding the flood-damaged products, he would contact me. He also stated that no products would be destroyed unless I was present.

Ted L. Anderson

TLA:rpp
6/14/79

Ted L. Anderson (252)
Investigator (SPG-RP)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS
U. S. Food and Drug Admin.
1009 Cherry
Kansas City, Mo. 64106

TO

2. NAME AND TITLE OF INDIVIDUAL
Mike Dake Production Supt.

3. DATE
6-8-79

4. FIRM NAME
Syntex Agribusiness, Inc. Nutrition and Chem. Div.

5. HOUR
— a.m.
1:10 p.m.

6. NUMBER AND STREET
1st Street

7. CITY AND STATE
Verona, Missouri

8. ZIP CODE
65769

Notice of Inspection is hereby given pursuant to Section 704(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374 (a)] [1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264].[2]

9. SIGNATURE *(Food and Drug Administration Employee(s))*
Ted L. Anderson

10. TITLE *(Food and Drug Administration Employee(s))*
Investigator

[1] Applicable portions of Section 704 of the Federal Food, Drug, and Cosemtic Act [21 U.S.C. 374] are quoted below:

Sec. 704. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, inspection shall extend to all things therein *(including records, files, papers, processes, controls, and facilities)* bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data *(other than data as to qualifications of technical and professional personnel performing functions subject to this Act)*, and (E) research data *(other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505 (j) of this Act)*. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262 – 264] are quoted below:

Part F-Licensing – Biological Products and Clinical Laboratories and******

Sec. 351 (c) "Any officer, agent, or employee of the Department of Health, Education, and Welfare, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – ***** Control of Radiation.

Sec. 360. A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests *(or testing programs)* required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a) (2) or 390(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records *(including testing records)*, make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

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(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a require-

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